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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,611	11/21/2001	Lorraine Faxon Meisner	36091-701.302	4194

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/990,611	MEISNER, LORRAINE FAXON	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-12,15-17,21,23-25 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,15-17,21,23-25 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claims are directed to a topical composition comprising 5 to about 25 w/v% ascorbic acid, zinc, water with a pH of about 3.5 to about 4.1 where part of the ascorbic acid is prepared by heating an ascorbic acid solution to obtain at least a 20% w/v, cooling and then combining the same with water, zinc an additional ascorbic acid and adjusting to about 3.5 to about 4.1. The description of the claims is applicable to both rejections below.

Claims 1,3-8, 10-12, 15-17, 21, 23-25, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Herstein (US Pat. 5,902,591), The Merck Index and Yaun et al..

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily (Column 2, lines 38-53, Column 3, Table 1, Column 4, lines 34-45, Claims 1, 2).

Murad teaches a composition for treatment of skin overexposed to sunlight and wrinkles comprising a sugar, such a N-acetylglucoseamine or glucoseamine, amino acids, such as cysteine, methionine or N-acetyl cysteine, ascorbic acid, and a zinc compound, such as zinc

sulfate (Column 4, lines 62-68, Columns 5, 6, Column 7, lines 30-41, Column 9, lines 3-7). It is taught that the composition may be formulated as a cream, paste, gel, ointment, solution or suspension in an aqueous liquid, oil-in-water emulsion or a water-in-oil emulsion by any methods of pharmacy which can be applied topically (Column 8, lines 43-49, Column 9, lines 34-45). It is taught that the sugar and amino acids assist in thickening the dermis and supplementing collagen and elastic tissues which reduces wrinkling and lines (Column 5, lines 5-18). It is taught that the addition of ascorbic acid inhibits collagenase and elastase, enzymes which break down collagen and elastic tissues, and assist in the reducing the occurrence of additional wrinkles and facilitate the healing of skin tissues (Column 5, lines 18-22). It is taught that zinc binds collagen fibers and inhibits elastase, an enzyme that also breaks down collagen and elastic tissue (Column 5, lines 22-24).

Herstein teaches that a pH within 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin and stabilize the ascorbic acid molecule (Column 2, lines 40-47, Column 10, lines 6-17).

The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius (page 111).

Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively (Pages 5081, 8082).

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc

sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily. The difference between Schinitsky et al. and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, non-toxic zinc salt, water, pH of 3.5 to 4.1 and the preparation process. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and zinc (Schinitsky et al.), the combination of zinc, ascorbic acid and aminosugar (Murad), the use of ascorbic acid up to 20% (Schinitsky et al.) and that a pH of 3.5 to 4.1 is preferred to facilitate entry of ascorbic acid into the skin (Herstein). Further, The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius and Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the pH range of 3.5 to 4.1 would facilitate entry of ascorbic acid into the skin and that the combination would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid by heating the ascorbic acid to around 60 degrees Celsius in order to facilitate the solubility of higher concentrations of ascorbic acid and then cool the solution to room temperature so as to inhibit degradation of the ascorbic.

The Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection.

With respect to the evidence of stability set forth on page 7 and the figures in the Specification, said evidence is not sufficient to overcome the rejection herein. The evidence presented consists of nuclear magnetic resonance spectra and the Applicant's conclusion that said spectra shows that pre-treated ascorbic acid is more stable than non-pretreated ascorbic acid. However, said evidence does not explain how the spectra supports said conclusion and no comparative data is presented in affidavit form from which the Examiner can review the data and determine if the Applicant's conclusions are valid such that the evidence overcomes the *prima facie* conclusion of obviousness.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,3-8, 10-12, 15-17, 21, 23-25, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schinitsky et al. (US Pat. 4,938,969) in view of Murad (US Pat. 5,804,594), Darr et al. (US Pat. 5,140,043), The Merck Index and Yaun et al..

Schinitsky et al. is cited and Murad are cited for the same reasons as above are incorporated herein to avoid repetition.

Darr et al. discloses that a pH of no more than about 3.5 ensures that greater than 82% of the ascorbic acid remains in the protonated, uncharged form and faciliates entry of ascorbic acid into the skin and stabilizes the ascorbic acid molecule (Column 3, lines 17-33, Column 4, lines 7-18, claims 1-42). Darr et al. discloses that at even at a pH of 4.5, a 5% solution of ascorbic acid

remains quite stable and that at a pH of 4.2, 5% ascorbic acid remained stable (Column 5, lines 1-27).

The Merck Index and Yaun et al. are cited for the same reasons as above and are incorporated herein to avoid repetition.

Schinitsky et al. teach a composition and method to reduce epidermal wrinkling resulting from photo-aging comprising ascorbic acid (about 2-20%), tyrosine (about 1-10%) and zinc sulfate (about 0.5-5%) in a pharmaceutically acceptable vehicle, for example, hydrophilic lotion, ointment, cream or gel, which can include propylene glycol, which is applied once or twice daily. The difference between Schinitsky et al. and the claimed invention is that the prior art does not expressly disclose the combination of at least 10% of ascorbic acid, aminosugar, non-toxic zinc salt, water, pH of 3.5 to 4.1 and the preparation process. However, the prior art amply suggests the same as the prior art discloses the combination of ascorbic acid and zinc (Schinitsky et al.), the combination of zinc, ascorbic acid and aminosugar (Murad), the use of ascorbic acid up to 20% (Schinitsky et al.) and that a pH of about 3.5 is preferred to facilitate entry of ascorbic acid into the skin (Darr et al.). Further, The Merck Index discloses that the solubility of ascorbic acid in hot water is 80% at 100 degrees Celsius and 40% at 45 degrees Celsius and Yaun et al. disclose that temperature is an important factor affecting the degradation rate of ascorbic acid and that while heated at 100 and 60 degrees Celsius for 2 hours the content of furfural in ascorbic acid solution (pH 4) was 2.88 and 0.01 mg/L, respectively, the content of 3-hydroxy-2-pyrone was 3.68 and 0.4 mg/L , and the content of 2-furoic acid was 0.56 mg/L and not detected, respectively. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the pH range of about 3.5 would facilitate entry of ascorbic acid into the skin and that the combination

would be effective in treating or protecting against skin damage due to exposure to the sun. Further, one of ordinary skill in the art would be motivated to prepare the ascorbic acid by heating the ascorbic acid to around 60 degrees Celsius in order to facilitate the solubility of higher concentrations of ascorbic acid and then cool the solution to room temperature so as to inhibit degradation of the ascorbic.

The Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection and the same reasons as above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
July 7, 2009

/John Pak/
Primary Examiner, Art Unit 1616